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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RONALD L. REAM, MICHAEL J. GREENBERG,
WILLIAM J. WOKAS, and CHRISTINE L. CORRIVEAU

Appeal 2009-001864
Application 09/990,628
Technology Center 1600

Decided:¹ July 17, 2009

Before DEMETRA J. MILLS, LORA M. GREEN, and
MELANIE L. McCOLLUM, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

STATEMENT OF CASE

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

According to Appellants,

[t]he present claims provide improved products for delivering a medicament or agent to an individual. To this end, chewing gum, specifically a coated chewing gum product, is provided including a medicament or agent. The medicament or agent is present within the coating. The coating substantially encloses a gum center (the water soluble portion and insoluble base portion) and comprises at least 50% by weight of the product. In other words, the coating comprising the medicament must have a weight equal to or greater than that of the gum center.

(App. Br. 11.)

By having a coating comprising at least 50% by weight of the entire chewing gum product, a larger amount of medicament or agent can be placed in the coating. As a result, chewing the gum releases more medicament or agent into the saliva in higher concentrations. See, specification, page 12, lines 22-24. A higher concentration of medicament or agent in the saliva results in a higher concentration gradient in the oral cavity. This improves absorption of the medicament or agent through the oral mucosa. See, specification, page 9, lines 5-20.

(App. Br. 11.)

The following claims are representative.

9. A chewing gum comprising:

a gum center; and

a coating comprising a medicament that surrounds the gum center, the coating comprising at least 50% by weight of the chewing gum product, the medicament being designed to be delivered into the systemic system of a patient.

18. A product including a medicament that is designed to function by being delivered through the systemic system of an individual comprising:

a chewing gum center; and

a coating that at least substantially surrounds the chewing gum center and comprises a medicament and a high-intensity sweetener, the coating comprising at least 50% by weight of the product.

Cited References

Cherukuri	US 4,317,838	Mar. 2, 1982
Stahl	WO 99/44436	Sept. 10, 1999

Grounds of Rejection

Claims 9-26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cherukuri in view of Stahl. Appellants did not provide separate arguments with respect to any claims other than claims 9 and 18. Consequently, these remaining claims fall together with representative claims 9 and 18. 37 C.F.R. § 41.37(c)(1)(vii).

ISSUE

The Examiner argues that one of ordinary skill in the art would have found it obvious at the time the invention was made to prepare gum base (gum center) and coat the gum base using taste masking agent and high

intensity sweetener taught by Cherukuri and include in the coating medicament taught by Stahl in analogous coated chewing gum preparations.

Appellants argue that the Examiner has failed to establish a prima facie case of obviousness because the cited references fail to show a gum coating comprising at least 50% by weight of the chewing gum product.

The issue is: Have Appellants demonstrated that the Examiner erred concluding that a gum coating comprising at least 50% by weight of the chewing gum product would have been obvious?

FINDINGS OF FACT

1. The Examiner finds that “[Cherukuri] teaches method for applying coating to chewing gum. See the abstract, see col. 2, lines 35-68, wherein the patent teaches coating syrup using sweeteners or bulking agents. This is same as claimed taste masking agent. [Cherukuri] at col. 2, lines 40-55 teaches that sweeteners to be coated using various ingredients.” (Ans. 3.)
2. According to the Examiner, “[t]his range disclosed in the patent for coating meets the claimed requirement of ‘coating comprising at least 50% of the chewing gum product’.” [Cherukuri], at col. 5, lines 10-19 teaches claimed high-intensity sweeteners. [Cherukuri], at col. 5, lines 6-8 teaches that the high-intensity sweetener can be present in the gum base or in the coating. [Cherukuri], at col. 5, lines 29-31 teaches gum base and the amount present by weight. [Cherukuri], col. 5, ll. 55-60 suggests, ‘in addition to chewing gum, the comestibles to be coated may include . . . other dosage

forms for medicinal or therapeutic use'. Medicinal are same as medicaments." (Ans. 3.)

3. The Examiner finds that "[Stahl] teaches coated chewing gum comprising a core of chewing gum and a coating comprising a coating material and one or more active substances. See the abstract, see page 1 under 'technical field', see also page 2. [Stahl] at page 3, last paragraph teaches active ingredients, which can be sweeteners. [Stahl] at page 8, lines 15- 17 teaches claimed high-intensity sweeteners. See also page 8, lines 20-24 wherein [Stahl] teaches that along with active substances other functional groups can also be incorporated. These functional groups include vitamins and nutrients along with various pharmaceuticals, which are described at paragraph bridging pages 9-10. [Stahl] at page 12 first paragraph teaches that the coating suspension comprise aqueous solution of xylitol, maltitol, isomalt, aspartame, acesulfame K and saccharin. These ingredients are claimed as taste masking agent." (Ans. 3-4.)
4. Stahl discloses that the core is coated with a coating suspension in approx. 2 to 90 increments to achieve a uniform coating with a suitable thickness. (Stahl, 12.) Stahl discloses that the coating process can be repeated as many times as needed in order to obtain the desired thickness of the coating. (Stahl, 3.)
5. Stahl discloses that using active substance in the coating provides a faster onset of the effect. (Stahl, 2.)

6. The Examiner finds that “it would have been obvious to one of ordinary skill in the art at the time the invention was made to make to prepare gum base (gum center) and coat the gum base using taste masking agent and high intensity sweetener taught by [Cherukuri] and include in the coating medicament taught by [Stahl] in analogous coated chewing gum preparations.” (Ans. 4.)
7. The Examiner finds that “[t]he idea of adding medicament into the coating flows logically from the art since one prior art teaches chewing gum coating using taste masking agent and high intensity sweetener and another prior art teaches chewing gum coating using active substances (high intensity sweetener), functional substances (medicaments) or sugar or sugar alcohols (taste masking agent).” (Ans. 4.)
8. The Examiner finds that “[o]ne of ordinary skill in the art would be motivated to coat the gum center with a medicament along with taste masking agent with the reasonable expectation of success that having medicament in the coating provides a better stability of the active substance (medicament) and increased effect thereof in all chewing phases.” (Ans. 4.)
9. The Specification, page 4, states that the coated chewing gum of the invention enhances the absorption of the drug into the systemic system as well as the bioavailability of the drug within the system.
10. Plasma caffeine delivered in a gum according to the invention provides a larger plasma absorption rate than for beverages containing caffeine. (Spec. 31.)

PRINCIPLES OF LAW

“[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious” the relevant inquiry is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

“[D]iscovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” *In re Boesch*, 617 F.2d 272, 276 (CCPA 1980). “[T]he discovery of an optimum value of a variable in a known process is normally obvious.” Exceptions to this rule include (1) the results of optimizing a variable were unexpectedly good and (2) the parameter optimized was not recognized in the prior art as one which would affect the results. *In re Antonie*, 559 F.2d 618, 620 (CCPA 1977). “It is well settled that mere duplication of parts has no patentable significance unless a new and unexpected result is produced.” *In re Harza*, 274 F.2d 669, 671 (CCPA 1960).

ANALYSIS

Claims 9 and 18 are essentially similar in claim scope and we address them together.

Appellants argue that:

Cherukuri is directed to a ... “one step” or “one syrup” method for providing a sugarless coating on a solid center, which includes applying alternating layers of coating syrup and dusting mix. See, *Cherukuri*, column 2, lines 14-30. As a result, rather than teaching overall coating levels, *Cherukuri* emphasizes the components of the coating syrup and dusting mix as well as specific ingredient percentages within the coating syrup and dusting mix. See, *Cherukuri*, column 2, lines 40-55 and column 3, line 51 to column 4, line 4.

(App. Br. 11). Appellants argue that:

[N]one of the weight percentages disclosed [in *Cherukuri*] teach a coating comprising at least 50% by weight of the overall product. Instead, the highest, and only, coating level disclosed in *Cherukuri* is 35 weight percent of the coated chewing gum tablet. See, *Cherukuri*, column 4, lines 29-34 and column 7, lines 13- 19. Therefore . . . *Cherukuri* fails to disclose or suggest a coating comprising at least 50% by weight of the chewing gum product as required, in part, by Claims 9 and 18.

(App. Br. 11.) “Appellants . . . submit that one having skill in the art would have no reason, in view of *Cherukuri*, to increase the coating level from a typical level of 35% to the presently claimed coating level of at least 50%.”

(App. Br. 8.)

We are not persuaded by Appellants’ arguments. Stahl discloses that the gum core is coated with a coating suspension in approximately 2 to 90 increments to achieve a uniform coating with a suitable thickness. (Stahl, 12.) Stahl also discloses that the coating process can be repeated as many

times as needed in order to obtain the desired thickness of the coating. (Stahl, 3.) Stahl discloses that using active substance in the coating provides a faster onset of the desired effect. (Stahl, 2.) Stahl discloses that active substances may be in the same or different layers and that combinations of active substances may include a medicament together with a substance that decreases the undesirable taste of the medicament, as in a taste masking agent. (Stahl, 3.)

Cherukuri teaches a method for applying coating to chewing gum. *See* the abstract, *see* col. 2, ll. 35-68, wherein the patent teaches coating syrup using sweeteners or bulking agents. This is a taste masking agent. Cherukuri, col. 2, ll. 40-55, teaches sweeteners present in gum coatings and other coating ingredients. Appellants further acknowledge that the coating level disclosed in Cherukuri is 35 weight percent of the coated chewing gum tablet. (Cherukuri, col. 4, ll. 29-34 and col. 7, ll. 13- 19.)

We agree with the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to coat a gum base (gum center) with a gum coating comprising at least 50% by weight of the chewing gum product. We also agree with the Examiner that it would have been obvious to use a taste masking agent and high intensity sweetener as taught by Cherukuri and include in the coating a medicament taught by Stahl in analogous coated chewing gum preparations. Stahl teaches that one of ordinary skill in the art would have known to coat a chewing gum core with a coating containing a medicament to the desired coating thickness. Stahl discloses that the coating process can be repeated as many times as needed in order to obtain the desired thickness of the coating. (Stahl, 3.)

Thus, Stahl teaches that it is known to those of skill in the art to vary the coating thickness on a gum center when the coating contains a medicament and that the coating process can be repeated as many times as needed.

Because it is an object of the invention of Stahl to use an active substance in the coating to provide a faster onset of the effect (Stahl, 2), and, in Stahl, the coating desirably contains a masking or flavoring agent to mask the taste of the medicament, one of ordinary skill in the art would have chosen a suitable coating thickness based on the amount of medicament to be delivered and the amount of flavoring agent required to mask the flavor of the medicament. Stahl teaches the incremental coating of the gum base up to 90 increments of coating.

Appellants have merely discovered an optimum value of coating depth of a result effective variable (coating depth to mask taste and deliver medicament at a faster onset of effect) in a known process of coating a gum center with a medicament. Thus, we further agree with the Examiner that one of ordinary skill in the art would modify the coating level from 35% of Cherukuri to at least 50% by weight of coating, since Stahl clearly teaches that coating process may be repeated to obtain the desired thickness. Stahl also teaches that the presence of the active substance in the coating of the coated chewing gum provides a fast onset of the effect, better stability of the active substance, and increased effect thereof in all chewing phases. (Ans. 4.)

We find that Appellants have not demonstrated that their additional gum coating is more than the predictable use of prior art coating elements according to their established functions.

CONCLUSION OF LAW

Appellants have not demonstrated that the Examiner erred in concluding that a coating comprising at least 50% by weight of the chewing gum product would have been obvious. The obviousness rejection is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

Ssc:

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